



Food and Drug Administration
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January 15, 2015

Hebei Grandaest Plastic Products Co., Ltd.
C/O Ms. Diana Hong
General Manager
Mid- Link Consulting Co., Ltd.
PO Box 120-119, Shanghai
CHINA

Re: K142703

Trade/Device Name: Powder-Free PVC Vinyl Patient Examination Gloves, Clear (non-colored)

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient examination glove

Regulatory Class: I

Product Code: LYZ

Dated: December 15, 2014

Received: December 19, 2014

Dear Ms. Diana Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (*if known*)

K142703

Device Name

Powder-free PVC Vinyl Exam Gloves

Indications for Use (*Describe*)

The Powder-free PVC Vinyl Exam Gloves are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

Type of Use (*Select one or both, as applicable*)

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Tab #2 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Submission: 01/06/2015

2. Sponsor Identification

Hebei Granded Plastic Products Co., Ltd.
Industrial Park, Julu County, Hebei Province, China

Establishment Registration Number: Not yet registered

Contact Person: Wei Liu
Position: Sale Manager
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3. Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu
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4. Proposed Device Identification

Proposed Device Name: Powder-free PVC Vinyl Exam Gloves

Proposed Device Common Name: Powder-free Exam Gloves

Regulatory Information:

Classification Name: Vinyl Patient Examination Glove;

Classification: I;

Product Code: LYZ;

Regulation Number: 21 CFR 880.6250;

Review Panel: General Hospital;

Intended Use Statement:

The Powder-free PVC Vinyl Exam Gloves are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

5. Predicate Device Identification

510(k) Number: K130733

Product Name: Benteng Power Free Vinyl Patient Examination Gloves, Clear (non-colored)

Manufacturer: Benteng Plastic Co., Ltd.

6. Device Description

The proposed devices, Powder-free PVC Vinyl Exam Gloves are non-sterile, non-colored and disposable medical gloves intended to be worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ASTM D5250-06 (Reapproved 2011), Standard Specification For Poly(Vinyl Chloride) Gloves For Medical Application.

ASTM D5151-06 (Reapproved 2011), Standard Test Method For Detection Of Holes In Medical Gloves.

ASTM D6124-06 (Reaffirmation 2011), Standard Test Method For Residual Powder On Medical Gloves.

ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin

sensitization.

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 1 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device(s)
Product Code	LYZ	LYZ
Regulation No.	21 CFR 880.6250	21 CFR 880.6250
Class	I	I
Intended Use	The Powder-free PVC Vinyl Exam Gloves are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner.	Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) is non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
Powdered or Powdered free	Powered free	Powered free
Size	S, M, L and XL	S, M, L and XL
Dimensions Length	Comply with ASTM D5250-06 (Reapproved 2011) > 230 mm	Comply with ASTM D5250-06 (Reapproved 2011) > 230 mm
Dimensions Width	Comply with ASTM D5250-06 (Reapproved 2011) S 85 ± 5mm M 95 ± 5mm L 105 ± 5mm XL 115 ± 5mm	Comply with ASTM D5250-06 (Reapproved 2011) S 85 ± 5mm M 95 ± 5mm L 105 ± 5mm XL 115 ± 5mm
Dimensions Thickness	Comply with ASTM D5250-06 (Reapproved 2011) Palm 0.10 ± 0.02mm Finger-tip 0.10 ± 0.02mm	Comply with ASTM D5250-06 (Reapproved 2011) Palm > 0.08mm Finger-tip > 0.05mm
Colorant	No colorant used	No colorant used
Single Use	Yes	Yes
Physical Properties	Before aging / after aging: Tensile Strength \geq 11Mpa,	Before aging / after aging: Tensile Strength \geq 11Mpa,

	Ultimate Elongation \geq 300% Comply with ASTM D5250-06 (Reapproved 2011)		Ultimate Elongation \geq 300% Comply with ASTM D5250-06 (Reapproved 2011)
Freedom from Holes	Comply with ASTM D5250-06 (Reapproved 2011) and ASTM D5151-06 (Reapproved 2011)		Comply with ASTM D5250-06 (Reapproved 2011) and ASTM D5151-06 (Reapproved 2011)
Residue Powder	0.6 +/- 0.1 mg per glove Comply with ASTM D5250-06 (Reapproved 2011)		< 2mg per glove Comply with ASTM D5250-06 (Reapproved 2011)
Compare performance data supporting substantial equivalence	Comply with ASTM D5250-06 (Reapproved 2011), ASTM D5151-06 (Reapproved 2011), ASTM D6124-06 (Reaffirmation 2011)		Comply with ASTM D5250-06 (Reapproved 2011), ASTM D5151-06 (Reapproved 2011), ASTM D6124-06 (Reaffirmation 2011)
Material	Main material: PVC Lubricant: PU		Main material: PVC Lubricant: PU
Biocompatibility	Sensitization	Under the conditions of this study, not a sensitizer	Comply with ISO 10993-10
	Irritation	Under the conditions of this study, not an irritant	
Sterilization	Non-sterile		Non-sterile
Label and Labeling	GuardFlex Powder Free PVC Vinyl Exam Gloves non sterile single use only Manufacturer and address Lot No. Avoid excessive heat This product is latex free Size, Quantity, Manufacture Date, Indications for Use		power free, patient examination glove devices color: clear (non-colored) non sterile single use only manufactured for lot

The proposed devices, Powder-free PVC Vinyl Exam Gloves are determined to be Substantially Equivalent (SE) to the predicate devices, Benteng Power Free Vinyl Patient Examination Gloves, Clear (non-colored) (K130733), in respect of safety and effectiveness.